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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,911	09/05/2003	Arturo J. Angel	524522000500	7674
25226 7590 10/17/2008 MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018				
EXAMINER				
CHANNAVAJALA, LAKSHMI SARADA				
ART UNIT		PAPER NUMBER		
1611				
MAIL DATE		DELIVERY MODE		
10/17/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/655,911

Applicant(s)

ANGEL ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 3, 4, 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of claims, response dated 7-18-08 and amendment and response dated 6-16-08 is acknowledged.

Upon careful consideration, the rejection of record has been replaced with the following new rejection:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 3, 4 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,962,532 to Campbell and Ann Jones et al (Clinical toxicology, abstract only) in view of Wholehealthmd and US 5910512 to Conant.

Campbell teaches methods and compositions for treating pain at a specific site with an effective amount of capsaicin. Campbell teaches that while capsaicin is effective in pain treatment, the side effects of capsaicin include activation of nociceptors in peripheral tissues desensitization of peripheral nociceptors, cellular degeneration of sensitive A-fiber and C-fiber etc (col. 1, col. 3-4). In order to overcome the above effects, Campbell teaches that anesthesia is first provided to the site of where capsaicin needs to be administered, followed by administration of capsaicin (summary of invention). Additionally, Campbell states that any irritant effect of capsaicin is relieved by administering a narcotic analgesic (see claim 9 of Campbell). Campbell fails to teach the claimed kit and also fails to teach the second component of instant claims.

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Wholehealthmd teaches a capsaicin product for relieving pain and arthritis. The reference suggests that capsaicin causes stinging and burning sensation, and suggests washing the hands thoroughly after applying the cream, with soapy water (page 3, special concerns). Wholehealthmd does not mention the solubility of capsaicin.

Ann Jones (abstract) studied the effect of cool tap water and oils in the removal of burning caused by capsaicin on the skins of elderly women. Ann Jones states that in a survey of elderly Hispanic women, treatment with oils or cool tap water were frequently used home remedies for burning caused by hot chili peppers. Twenty female subjects immersed their hands in standardized slurry of green chili for 40 minutes; afterwards one hand was placed in cool tap water and the other in vegetable oil for a total of 75 minutes. Pain was scored using a visual analog scale while the hands were immersed in the chili slurry, test baths, and after drying. The difference in pain score was calculated for each subject. Analysis was by pooled regression cool tap water immersion initially provided more relief while vegetable oil provided better long-term relief from the pain of "chili burns".

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include a component such as vegetable oil of Ann Jones or any suitable solubilizer which solubilizes and removes the residual capsaicin after applying, in the teachings of Campbell, because Wholehealthmd suggests removing capsaicin to avoid burning and stinging and Conant teaches that capsaicin is insoluble in water but is soluble in alcohol, oils, grease,

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chloroform etc. A skilled artisan would have employed a suitable solvent such as oils of Anne Jones to remove capsaicin of Campbell because Anne Jones teaches that vegetable oils are very effective in providing long term relief from the burning pain caused by chili peppers, which by applicants' own admission (page 1, [0003]) contains capsaicin and causes burning. A skilled artisan would have expected to reduce burning caused by capsaicin of Campbell, by 1) desensitizing with an anesthetic as well as 2) removing the burning pain caused by capsaicin from the skin with vegetable oils. In this regard, Conant teaches that capsaicin is solubilized in oils, grease, chloroform etc (col. 1, L 35-41). With respect to the claimed solubility, Anne Jones teaches oils for reducing burning for a long time and therefore the burden is on applicants to show that oils do not possess the claimed solubility for capsaicin.

While the cited references fail to teach a kit and a separately packaged second composition with the claimed solubility of capsaicin in the second composition, it would have been obvious for a skilled artisan to first apply capsaicin for its intended pharmacological effect and then apply a soap or an oily solution to remove the irritant effect so as to allow the effect of capsaicin be achieved. Further, the solution intended to remove the irritant effect of capsaicin should have to be solubilizing capsaicin so as to successfully remove the irritant effect.

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2. Claims 1, 3, 4 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over unpatentable US 2002/0002406 Robbins et al (PTO-1449 of 3-14-08) and Ann Jones et al in view of Wholehealthmd and US 5910512 to Conant.

Robbins teaches application of capsaicin or its analogs for treating pain, including neuropathic pain. Robbins teaches capsaicin or its analogue is applied to the skin in the form of a transdermal patch containing greater than 5% to 10% capsaicin (0008-0010; 0012). The steps of application in example 1 describes applying an anesthetic (ELMA- see 0012 for description), followed by capsaicin and removal of the capsaicin. Instant description at 0045 describes the same capsaicin anesthetics as that of Robbins. Robbins teaches that while capsaicin is effective in treating neuropathic pain, it also causes side effects such as burning and therefore suggests applying a desensitizer of C fibers, such as an anesthetic so the burning would be reduced.

Robbins fails to teach the claimed kit and a second component to solubilize capsaicin and the instructions of use.

The teachings of Anne Jones, Wholehealthmd and Conant are described in the preceding paragraphs.

It would have been obvious for one of ordinary skill in the art at the time of the instant invention to include a component such as vegetable oil of Ann Jones or any suitable solubilizer which solubilizes and removes the residual capsaicin after applying, in the teachings of Robbins, because Wholehealthmd suggests removing capsaicin to avoid burning and stinging and Conant teaches

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that capsaicin is insoluble in water but is soluble in alcohol, oils, grease, chloroform etc. A skilled artisan would have employed a suitable solvent such as oils of Anne Jones to remove capsaicin of Robbins because Anne Jones teaches that vegetable oils are very effective in providing long term relief from the burning pain caused by chili peppers, which by applicants' own admission (page 1, [0003]) contains capsaicin and causes burning. A skilled artisan would have expected to reduce burning caused by capsaicin of Robbins, by 1) desensitizing with an anesthetic as well as 2) removing the burning pain caused by capsaicin from the skin with vegetable oils. In this regard, Conant teaches that capsaicin is solubilized in oils, grease, chloroform etc (col. 1, L 35-41). With respect to the claimed solubility, Anne Jones teaches oils for reducing burning for a long time and therefore the burden is on applicants to show that oils do not possess the claimed solubility for capsaicin.

While the cited references fail to teach a kit and a separately packaged second composition with the claimed solubility of capsaicin in the second composition, it would have been obvious for a skilled artisan to first apply capsaicin for its intended pharmacological effect and then apply a soap or an oily solution to remove the irritant effect so as to allow the effect of capsaicin be achieved. Further, the solution intended to remove the irritant effect of capsaicin should have to be solubilizing capsaicin so as to successfully remove the irritant effect.

Response to Arguments

3. Applicant's arguments with respect to claims 1, 3, 4 and 10-13 have been considered but are moot in view of the new ground(s) of rejection.
4. With respect to the unexpected results presented in example 4 of the specification and the results employing various antibacterial soap solutions, instant claims are not limited to any specific solvent that solubilizes capsaicin, whereas the results presented only shows with PEG and carbopol. Further, Conant and Ann Jones teach oils are suitable for solubilizing capsaicin and removing the burning pain of chili respectively.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM - 5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner,
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October 13, 2008